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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/828,302 | 04/06/2001 | Oswaldo da Costa e Silva | 16313-0029 | 6582 |

29052 7590 08/27/2002

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| EXAMINER |
|---|
| COLLINS, CYNTHIA E |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | 10 |

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/828,302 | Applicant(s) DA COSTA E SILVA ET AL. | |
|---|---|---|---|
| | Examiner Cynthia Collins | Art Unit 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *13-16 and 27-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-12 and 17-26, and Invention D, SEQ ID NOS: 9 and 14 (PP2C-1), in Paper No. 9 is acknowledged. The traversal is on the ground(s) that examination of the nine groups would not be an undue burden because of their close technological relationship. The traversal is also on the grounds that the PHSRP coding nucleic acids are not independent and distinct.

This is not found persuasive because while the search of Group I may overlap with the search of Groups II-IX, their searches are not coextensive of each other. In this particular instance, the searches of Group II-IX are not coextensive with a search of Group I, since Group II requires a search for an agricultural product not claimed in Group I, Group III requires a search for an isolated PHSRP protein not claimed in Group I, Group IV requires a search for methods of increasing stress tolerance by modifying the expression of PHSRP in a nontransgenic plant, said methods not claimed in Group I, Group V requires a search for methods of increasing stress tolerance by modifying the expression of PHSRP in a transgenic plant, said methods not claimed in Group I, Group VI requires a search for methods of decreasing stress tolerance by modifying the expression of PHSRP in a nontransgenic plant, said methods not claimed in Group I, Group VII requires a search for methods of decreasing stress tolerance by modifying the expression of PHSRP in a transgenic plant, said methods not claimed in Group I, Group VIII requires a search for methods of decreasing stress tolerance in a nontransgenic plant by administration of an antisense molecule, said methods not claimed in Group I, and Group IX requires a search for methods of decreasing stress tolerance in a transgenic plant by

administration of an antisense molecule, said methods not claimed in Group I. The second argument is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are either independent *or* distinct (MPEP § 803). Furthermore, each of the PHSRP sequences claimed requires a separate search. Claims 13-16 and 27-40 and the nonelected sequences are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

### *Information Disclosure Statement*

An initialed and dated copy of Applicant's IDS form 1449, filed July 9, 2001, Paper No. 3, is attached to the instant Office action.

### *Claim Objections*

Claims 4, 5, 6, 18, 19, 24, 25 and 26 are objected to because they recite the sequences of nonelected inventions. Appropriate correction is required.

Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7-12, 17 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to transgenic plant cells transformed with a Phosphatase Stress-Related Protein coding nucleic acid, including a Protein Phosphatase 2C (PP2C) coding nucleic acid and a Protein Phosphatase 2C-1(PP2C-1) coding nucleic acid and orthologs thereof. The claims are also drawn to a transgenic plant and seed, an isolated nucleic acid encoding a Phosphatase Stress-Related Protein, and a method of producing a transgenic plant using an isolated nucleic acid encoding a Phosphatase Stress-Related Protein.

The specification describes only five isolated DNA molecules that encode proteins homologous to known phosphatases and that improve drought and freezing stress tolerance when expressed in transgenic plants, the elected nucleic acid of SEQ ID NO: 9 isolated from *Physcomitrella patens* that encodes the protein of SEQ ID NO: 14 (PP2C-1), and the nonelected nucleic acids of SEQ ID NOS: 6,7,8, and 10 isolated from *Physcomitrella patens* that encode the proteins of SEQ ID NOS: 11,12,13 and 15 (PP2A-2, PP2A-3, PP2A-4, PP2C-2) (page 46 Table 1; page 58 Table 9; page 59 Table 10). This does not constitute a substantial portion of the genera that comprise Phosphatase Stress-Related Protein coding nucleic acids, Protein Phosphatase 2C (PP2C) coding nucleic acids and orthologs thereof, or Protein Phosphatase 2C-1(PP2C-1) coding nucleic acids and orthologs thereof, each of which increase tolerance to an environmental stress when expressed in a transgenic plant cell. Each of the the claimed genera

encompass a multitude of different nucleotide sequences and proteins, including those yet to be discovered. The disclosure of only five isolated DNA molecules that encode proteins homologous to known phosphatases and that improve drought and freezing stress tolerance when expressed in transgenic plants does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1-12 and 17-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant transformed with a nucleic acid of SEQ ID NO:9 encoding PP2C-1 polypeptide of SEQ ID NO:14, said plant exhibiting increased tolerance to drought and freezing stress, does not reasonably provide enablement for transgenic plants transformed with other Phosphatase Stress-Related Protein coding nucleic acids, said plants exhibiting tolerance to environmental stresses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to transgenic plant cells transformed with a Phosphatase Stress-Related Protein coding nucleic acid, including a Protein Phosphatase 2C (PP2C) coding nucleic acid and a Protein Phosphatase 2C-1(PP2C-1) coding nucleic acid and orthologs thereof, a PP2C-1 nucleic acid encoding SEQ ID NO:14, a PP2C-1 coding nucleic acid of SEQ ID NO:9 and a PP2C-1 coding nucleic acid that hybridizes under stringent conditions to SEQ ID NO:9.

The claims are also drawn to a transgenic plant and seed, an isolated nucleic acid encoding a Phosphatase Stress-Related Protein, and a method of producing a transgenic plant using an isolated nucleic acid encoding a Phosphatase Stress-Related Protein.

The specification discloses the elected nucleic acid of SEQ ID NO:9 isolated from *Physcomitrella patens* that encodes a protein (PP2C-1) of SEQ ID NO:14 having amino acid sequence homology to known eukaryotic phosphatase 2Cs (page 46 Table 1; page 49 Table 5). The specification also discloses that expression of a nucleic acid of SEQ ID NO:9 in transgenic *Arabidopsis* increases the plant's tolerance to drought stress and freezing stress as compared to nontransformed control plants (page 58 Table 9 and page 59 Table 10). Additionally, on pages 62-63 the specification discloses that expression of a nucleic acid of SEQ ID NO:9 in transgenic soybean increases the plant's tolerance to drought stress, freezing stress and/or salinity stress as compared to nontransformed control plants, although the recitation of "and/or" on page 63 line 4 makes it is unclear which of the stresses the transgenic soybeans actually exhibit increased tolerance to.

While one of skill in the art could readily make transgenic plants expressing any polynucleotide encoding a polypeptide having homology to known phosphatases, it would require undue experimentation for one skilled in the art to determine which polynucleotide to express and at what level, because the ability of such a polynucleotide to confer stress tolerance in a transgenic plant is unpredictable. The specification does not provide sufficient guidance for one skilled in the art to determine which polynucleotide to express and at what level, because the specification teaches only four other polynucleotides encoding a protein having homology to known phosphatases that can increase stress tolerance when expressed in a transgenic plant.

Also, while one of skill in the art could readily make transgenic plants comprising any polynucleotide encoding a polypeptide having homology to known phosphatases, it would require undue experimentation for one skilled in the art to determine how to express such a polynucleotide in a manner that would increase tolerance to stresses other than drought or freezing, because the specification does not teach how to express a polynucleotide encoding a phosphatase such that tolerance to stresses other than drought or freezing is increased. Furthermore, the specification does not disclose the structure of any Protein Phosphatase 2C ortholog, and such orthologs cannot be predicted from Applicant's disclosure, as orthologs by definition have evolved to become "different" from each other. The specification does not provide sufficient guidance for one skilled in the art to identify, without undue experimentation, Protein Phosphatase 2C orthologs that could be used to practice the claimed invention. Additionally, the specification does not disclose the effect of expressing a polynucleotide encoding a polypeptide having homology to known phosphatases on environmental stress tolerance in any host cell type other than a plant cell. While one of skill in the art could readily transform other types of host cells, such as bacteria, yeast, mammalian, etc., and express any polynucleotide encoding a polypeptide having homology to known phosphatases, it would require undue experimentation for one skilled in the art to identify which type of host cell to transform, and how to express the polynucleotide in that cell such that environmental stress tolerance of the host cell is increased, because the ability of such a polynucleotide to confer stress tolerance in host cells other than plant cells is unpredictable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 17-19 and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 17-19 and 21-26 are indefinite in the recitation of "Stress-Related Protein" or "PHSRP", because the relationship between stress and the protein is unclear.

Claims 1 and 21 are indefinite in the recitation of "environmental stress". It is unclear what type of environmental stress the cell would have increased tolerance to, as a change in any environmental parameter may be a source of stress to a cell.

Claims 6 and 26 are indefinite in the recitation of "hybridizes under stringent conditions". It is unclear what conditions would yield the claimed nucleic acid molecules, as those skilled in the art define stringency differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 10 is indefinite in the recitation of "forage crop", as a forage crop is not a plant.

Claim 12 is indefinite in the recitation of "true breeding", as it is unclear how a seed would be "true breeding".

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 12 is drawn to seed, but is not limited to seed that comprise the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that plant. In addition, even though the claim recites that the seed is true breeding for an increased tolerance to an environmental stress, a native gene independent of the transgene introduced into the parent could confer such a trait, given that there is no indication that there would be any other distinguishable characteristics of the claimed seed, it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the seed comprises the construct that was introduced into the parent plant would overcome the rejection.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
August 24, 2002

Phuong Bui

PHUONG T. BUI
PRIMARY EXAMINER

8/26/02